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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,785	10/06/2003	Lyn Hughes	A01290B	3718
21898 ROHM AND H	90 10/26/2007 A S COMPA NV		EXAM	INER
PATENT DEP	ARTMENT		AZPURU, CARLOS A	
	100 INDEPENDENCE MALL WEST PHILADELPHIA, PA 19106-2399		ART UNIT	PAPER NUMBER
			1615	
			MAIL DATE	DELIVERY MODE
			10/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
	10/679,785	HUGHES, LYN
Office Action Summary	Examiner	Art Unit
	Carlos A. Azpuru	1615
The MAILING DATE of this communication	<u>'</u>	ith the correspondence address
Period for Reply		
A SHORTENED STATUTORY PERIOD FOR RE WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFF after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory per - Failure to reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the meanned patent term adjustment. See 37 CFR 1.704(b).	B DATE OF THIS COMMUNION (1.136(a). In no event, however, may a residual will apply and will expire SIX (6) MON (atute, cause the application to become AB	CATION. reply be timely filed ITHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133).
Status	•	
1) Responsive to communication(s) filed on <u>0</u> 8	8 August 2007.	
2a)⊠ This action is FINAL . 2b)☐ T	his action is non-final.	
3) Since this application is in condition for allo		
closed in accordance with the practice unde	er <i>Ex parte Quayle</i> , 1935 C.D	0. 11, 453 O.G. 213.
Disposition of Claims	•	·
4)⊠ Claim(s) 10 and 13 is/are pending in the ap	plication.	
4a) Of the above claim(s) is/are without	drawn from consideration.	
5) Claim(s) is/are allowed.		
6)⊠ Claim(s) <u>1,3,4 and 10</u> is/are rejected.	•	
7)⊠ Claim(s) <u>5-9</u> is/are objected to.		•
8) Claim(s) are subject to restriction an	d/or election requirement.	·
Application Papers		
9)☐ The specification is objected to by the Exam	iner.	
10) The drawing(s) filed on is/are: a) a	accepted or b) objected to	by the Examiner.
Applicant may not request that any objection to	the drawing(s) be held in abeyar	nce. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the cor	rection is required if the drawing	(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the	Examiner. Note the attached	d Office Action or form PTO-152.
Priority under 35 U.S.C. § 119		•
12) Acknowledgment is made of a claim for fore a) All b) Some * c) None of:	ign priority under 35 U.S.C. §	§ 119(a)-(d) or (f).
1. Certified copies of the priority docum	ents have been received.	·
2. Certified copies of the priority docum		· · · · · · · · · · · · · · · · · · ·
3. Copies of the certified copies of the p		received in this National Stage
application from the International Bur	, , , , , , , , , , , , , , , , , , , ,	
* See the attached detailed Office action for a	list of the certified copies not	received.
Attachment(s)		
1) Notice of References Cited (PTO-892)		Summary (PTO-413)
 Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO/SB/08) 	5) D Notice of I	s)/Mail Date nformal Patent Application
Paper No(s)/Mail Date	6) 🔲 Other:	<u></u> ·

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DETAILED ACTION

Receipt is acknowledged of the amendment filed 08/08/2007.

The rejections under 35 USC 112, first paragraph for written description and scope of enablement, as well as the rejection under 35 USC 102(b) are hereby withdrawn.

The following rejection is maintained in this action:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4 and 10 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 10 of

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copending Application No. 10/713,926 (US'926). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'926 claims the combination of an resinate of an opiate (a known controlled substance) in an oral dosage form (claim 1), which may additionally have an aversive agent added (claim 10). As such, those of ordinary skill would have found it well within their skill to claim the instant pharmaceutical which combines a resinate of a drug and an aversive agent with a reasonable expectation of similar aversive results if the dosage form is tampered with intent to abuse the drug. The instant claims would have been obvious to one of ordinary skill in the art given the claims of US'926.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 08/08/2007 have been fully considered but they are not persuasive.

Applicant argues that neither application has been patented. That is correct. However, this is not the last rejection in this case, and the application can not be allowed at this time.

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The following is a new rejection in response to applicant's amended claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Regarding claim 3, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

See MPEP § 2173.05(d).

Claims 5-9 are objected to as dependent upon a rejected base claim.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) of 571-272-1000.

Carlos A. Azpukú Primary Examiner

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